

## **REMARKS**

Claims 1, 3-5, 16-17, 20 and 22-24 are being examined. Claims 2, 6-15, 18-19 and 21 have been withdrawn. Claims 1, 17 and 22 have been amended. Support for the amendments to claim 1 may be found throughout the specification, see for example, page 10, lines 10-11 and 15-16. No new matter has been added.

Favorable reconsideration is respectfully requested.

### **I. Interview Summary**

Applicants kindly thank the Examiner for the discussion of the species election in the application in the telephonic interview with Heidi Dare on May 5, 2010 and on June 3, 2010. No references were discussed and no demonstration was given. No agreement was reached regarding the pending claims.

### **II. Drawing Objections**

New sheets of drawings in compliance with 37 C.F.R. §1.121(d) are required by the Examiner for examination of the application.

New sheets of replacement drawings were previously submitted on September 22, 2010 in compliance with 37 C.F.R. §1.121(d) and 37 C.F.R. §1.84 (c) and in compliance with the two month deadline.

Applicants respectfully request that the objection to the drawings be withdrawn.

### **III. Claim Rejections under 35 U.S.C. §112**

Claim 17 has been rejected under 35 U.S.C. §112, second paragraph, as being indefinite for reciting "the release means for disengaging the first locking means comprises two positions placed on opposite sides of the housing."

Applicants have amended claim 17 to remove the term "for disengaging the first locking means."

Applicants respectfully request that the rejection of claim 17 under 35 U.S.C. §112, second paragraph, be withdrawn.

#### **IV. Claim Rejections under 35 U.S.C. §102**

##### **A. Tsals et al.**

Claims 1, 3-5, 16-17, 20 and 22-24 have been rejected under 35 U.S.C. §102(b) as being anticipated by Tsals et al. (U.S. 5,858,001, "Tsals").

Applicants respectfully traverse the rejection of claims 1, 3-5, 16-17, 20 and 22-24 as being anticipated by Tsals in light of the amendment to claim 1 and traversals discussed below.

Claim 1 requires an insertion needle unreleasably fastened to and moving together with the slidable member and a pivoting member fastened to and moving together with the slidable member. Claim 22 requires an insertion member unreleasably connected to the slidable member and a pivoting member operably connected to the slidable member.

Tsals is directed to a cartridge-based drug delivery device. The device of Tsals includes a piston 16 within a cartridge 12. (Col. 8, line 21.) A needle assembly including needle 21 is mounted on the cartridge 12. (Col. 8, lines 26-28.) Plate 25 pushes piston 16 to compress the drug compartment 17. (Col. 9, lines 9-10.) Tsals discloses that cartridge 12 is connected to member 13 by means of a living hinge. (Col. 8, lines 39-40.) Downward pressure on the upper surface 30 by means of the hinge 28 causes the delivery needle 21 to pass through the aperture 29 and penetrate the skin. (Col. 8, lines 61-62.) As shown in FIGS. 1 and 2, the needle 21 of Tsals does not move together with the piston 16 and is not unreleasably fastened to the piston 16. In addition, the hinge 28 is not connected to or movable with the piston 16. Tsals fails to teach or suggest an insertion needle unreleasably fastened to and moving together with the slidable member. Tsals further fails to teach or suggest a pivoting member connected to and moving together with the slidable member. Tsals clearly fails to teach each element of claims 1 and 22 as required by §102.

Therefore, Applicants respectfully request that the rejection of 1, 3-5, 16-17, 20 and 22-24 under 35 U.S.C. §102(b) be withdrawn.

**B. Marano et al. or Safabash et al.**

Claims 1, 3-5, 16-17, 20 and 22-24 have been rejected under 35 U.S.C. §102(b) as being anticipated by Marano et al. (U.S. 5,851,197, "Marano") or in the alternative Safabash et al. (U.S. 2006/0069351 "Safabash").

Applicants respectfully traverse the rejection of claims 1, 3-5, 16-17, 20 and 22-24 as being anticipated by Marano or in the alternative Safabash in light of the amendment to claim 1 and traversals discussed below.

As discussed above, claim 1 requires an insertion needle unreleasably fastened to and moving together with the slidable member and a pivoting member fastened to and moving together with the slidable member. Claim 22 requires an insertion member unreleasably connected to the slidable member and a pivoting member operably connected to the slidable member.

Marano and Safabash are directed to injectors for a subcutaneous infusion set. Safabash is a continuation-in-part of Marano et al. Both Marano and Safabash are directed to an injector 10 provided for quick and easy transcutaneous placement of a removable medical needle, particularly such as an insertion needle 12 of the type provided with a subcutaneous infusion set 14 as depicted in FIGS. 4 and 7. (Col. 4, lines 13-17, Marano.) The removable needle 12 is shown in FIG. 4 of Marano and in FIG. 43 referred to by the Examiner in Safabash. According to Marano, the safety lock arms prevent projection of the infusion set (including the separable needle) from the injector in the event that the trigger member is actuated with the nose end of the barrel spaced from the skin of a patient. (Col. 2, lines 30-33, Marano.) In the embodiment referred to by the Examiner in Safabash, the insertion device 600 is provided to insert an insertion set 700 including a piercing member 702 of the insertion set 700. (Paragraphs 108, 109, Safabash.) The carrier body 602 has a receiving structure for the insertion set 700 that includes a recess 606 and bore 608 adapted to hold the piercing member hub 704 by slight interference fit. As described in the summary of Safabash, the receiving structure may include a safety retainer structure that retains the at least one piercing member on the receiving structure during movement from the retracted position to the advanced position. This safety retainer structure permits

separation of the at least one piercing member from the carrier body when the carrier body is in the advanced position. (Paragraph 16, Safabash.) In addition, the embodiment shown in FIGS. 41-46 fails to teach or suggest any pivoting member fastened to and moving together with the slidable member. Clearly, Marano and Safabash fail to teach or suggest at least an insertion needle (member) unreleasably fastened to (connected to) and moving together with the slidable member.

In contrast, claim 1 requires an insertion needle unreleasably fastened to and moving together with the slidable member and a pivoting member fastened to and moving together with the slidable member. Claim 22 requires an insertion member unreliably connected to the slidable member. Marano and Safabash fail to teach every element of claims 1 and 22 as required by §102.

Therefore, Applicants respectfully request that the rejection of 1, 3-5, 16-17, 20 and 22-24 under 35 U.S.C. §102(b) be withdrawn.

#### **V. Summary**

Having carefully addressed all the rejections of the Examiner in the July 23, 2010 Office Action, it is respectfully asserted that the claims properly define the invention and that the invention is both novel and non-obvious. Allowance of the present claims is earnestly solicited.

Applicants respectfully request that the Examiner call the undersigned with any questions regarding this response to expedite the prosecution of the application.

Respectfully submitted,



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